

Shining Mountain Herbs
Ridgway, CO 81432

May 10, 2005

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., Washington, D.C. 20204

RE: 21 U.S.C. 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir or Ma'am:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Organic Hawthorn CardioCare, a dietary supplement. Shining Mountain Herbs is the manufacturer of Organic Hawthorn CardioCare.

Statements being made in the labeling of Organic Hawthorn CardioCare are as follows:

- Organic Hawthorn CardioCare
- Shining Mountain Herbs
- The majority of the herbs in this CardioCare formula are grown on our family farm high in the Rocky Mountains. We use organic, sustainable and mindful growing practices. The remaining herbs come from the highest quality sources we can find.
- Certified Organic by the Colorado Department of Agriculture
- Supports Healthy Heart Function*
- * This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.
- We create our organic products for your optimal health.
- Signed Tim and Sheila
- Portions of our proceeds go to support the American Herbal Pharmacopoeia.
- Warning: Do not use this product in pregnancy unless directed by a qualified health care professional. Consult your health care professional before taking this product.
- Keep out of reach of children.
- Serving size: 35 Drops (1 ml)**
- Servings Per Container: 120
- Calories: 6
- Suggested Use: 1 ml two to three times per day or as directed by your health care professional. Shake well before use. Do not use if safety seal is broken or missing.

5636 County Road 23, Ridgway CO 81432 PH: 970-316-0008 FAX: 970-626-3346

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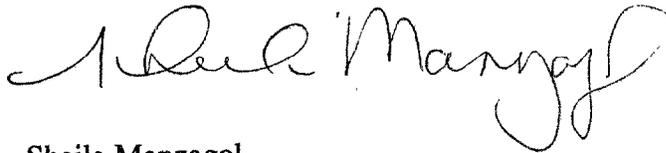
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Organic Hawthorn CardioCare
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- Amount per serving: Proprietary Blend contains 1 g of total herb per 5 ml extract.
- ** Daily Value Not Established.
- Ingredients: Hawthorn Berry, Leaf and Flower (Og), Motherwort Leaf and Flower (Og), Chinese Salvia Root, Tienche Ginseng Root, Dong Quai Root (Og), Juniper Berry (Og), Cinnamon Bark (Og).
- (Og) Organic
- Other Ingredients: Organic grain alcohol (40-60%), and purified Rocky Mountain water.
- Herbal Dietary Supplement
- 4 fl. oz.
- Lot#

To the best of my knowledge and belief, and based upon information available at the time of execution of this notice, I certify that the above information is accurate and complete. Shining Mountain Herbs possesses substantiation that the statements are truthful and not misleading.

Sincerely,



Sheila Manzagol
President
Shining Mountain Herbs